92. (New) The composition of claim 91, wherein the clot-busting drug is streptokinase.

93. (New) The composition of claim 78, wherein the AV blocker is adenosine.

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1-8 and 44-93 are pending after entry of the amendments set forth herein.

Claims 9-43 are hereby cancelled without prejudice with renewal, without intent to acquiesce to any rejection that may be applied thereon, and without the intent to abandon any subject matter encompassed therein.

Replace claims 1-8 with the clean version provided in the "clean copy". The changes are shown in the attached "Version with Markings to Show Changes Made".

New claims 44-93 are hereby added.

No new matter has been added.

Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number FREE001.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 1/10/02

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please cancel claims 9-43 without prejudice. Please amend claims 1-8 and add new claims 44-93 as follows.

1. (Amended) A method for arresting, protecting [and/]or preserving an organ which includes administering effective amounts of (i) a potassium channel opener or agonist [and/]or an adenosine receptor agonist and (ii) local anaesthetic to a subject in need thereof.

2. (Amended) [A] The method [as claimed in] of claim 1, wherein the organ is either intact in the body of the subject or is isolated.

3. (Amended) [A] The method [as claimed in] of claim 1, wherein the organ is a circulatory organ, respiratory organ, urinary organ, digestive organ, reproductive organ, neurological organ or somatic cell.

4. (Amended) [A] The method [as claimed in] of claim 3, wherein the circulatory organ is a heart.

5. (Amended) [A] The method [as claimed in] of claim 4, which is used to arrest, protect [and/]or preserve the heart during open-heart surgery, reduce heart damage before, during or following cardiovascular intervention or protect those portions of the heart that have been starved of normal flow, nutrients [and/]or oxygen.

6. (Amended) [A] The method [as claimed in any one] of claim[s] 1 [to 5], wherein the potassium channel opener or agonist is selected from nicorandil, diazoxide, minoxidil, pinicadil, aprikalim, cromokulim, NS-1619 (1,3-dihydro-1-[2-hydroxy5(trifluoromethyl)phenyl]5-(trifluoromethyl)2-H-benimidazol-one), amlodipine, Bay K 8644(L-type), (1,4-dihydro-26-dimethyl-5-nitro-4[2(trifluoromethyl)phenyl]-3-pyridine carboxylic acid (methyl ester)), bepridil HCI (L-type), calciseptine (L-type), omega-conotoxin GVIA (N-type), omega-conotoxin MVIIC (Q-type),

cyproheptadine HC1, dantrolene sodium (Ca^{2+} release inhibitor), diltiazem HC1 (L-type), filodipine, flunarizine HC1 (Ca^{2+}/Na^{+}), fluspirilene (L-type), HA-1077 2HC1(1-(5 isoquinolinyl sulphonyl) homo piperazine.HCI), isradipine, loperamide HC1, manoalide (Ca^{2+} release inhibitor), nicardipine HC1 (L-type), nifedipine (L-type), niguldipine HC1 (L-type), nimodipine (L-type), nitrendipine (L-type), pimozide (L- and T- type), ruthenium red, ryanodine (SR channels), taicatoxin, verapamil HC1 (L-type), methoxy-verapamil HC1 (L-type), YS-035 HC1 (L-type)N[2(3,4-dimethoxyphenyl)ethyl]-3,4-dimethoxy N-methyl benzene ethaneamine HC1) and AV blockers.

7. (Amended) [A] The method [as claimed in] of claim 6, wherin the AV blocker is adenosine.

8. (Amended) [A] The method [as claimed in] of claim 1 [or 2], wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S^*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-y1]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

Claims 9- 43 are cancelled.

44. (New) The method of claim 3, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S^*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-y1]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

45. (New) The method of claim 4, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine

(CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-y1]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

46. (New) The method of claim 5, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-y1]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

47. (New) The method of claim 6, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-y1]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

48. (New) The method of claim 7, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-y1]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

49. (New) The method of claim 8, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine

(CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

50. (New) The method of claim 44, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

51. (New) The method of claim 45, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

52. (New) The method of claim 46, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

53. (New) The method of claim 47, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine

(CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

54. (New) The method of claim 48, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

55. (New) The method of claim 49, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

56. (New) The method of claim 50, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

57. (New) The method of claim 1, wherein the local anaesthetic is selected from mexiletine, diphenylhydantoin, prilocaine, procaine, mipivacaine and Class 1B antiarrhythmic agents.

58. (New) The method of claim 51, wherein the class 1B antiarrhythmic agent is lignocaine.

59. (New) The method of claim 1, wherein active ingredients (i) and (ii) are administered together with a pharmaceutically acceptable carrier, diluent, adjuvant or excipient.

60. (New) The method of claim 53, wherein the pharmaceutically acceptable carrier, diluent, adjuvant or excipient is a buffer having a pH of about 6 to about 9.

61. (New) The method of claim 54, wherein the pharmaceutically acceptable carrier, diluent, adjuvant or excipient is a buffer having a pH of about 6 to about 9.

62. (New) The method of claim 54, wherein the pharmaceutically acceptable carrier, diluent, adjuvant or excipient has low concentrations of potassium.

63. (New) The method of claim 62, wherein the concentration of potassium is up to about 10mM.

64. (New) The method of claim 57, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (CGS-21680), 2-chloradenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a,2b,3b,4a(S^*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579), N^6-(R)-phenylisopropyladenosine (R-PLA), aminophenylethyladenosine 9APNEA) and cyclohexladenosine (CHA).

65. (New) The method of claim 60, wherein the buffer is Krebs-Henseleit, St. Thomas No. 2 solution, Tyrodes solution, Fremes solution, Hartmanns solution or Ringers-Lactate.

66. (New) The method of claim 59, wherein the pharmaceutically acceptable carrier, diluent, adjuvant or excipient has low concentrations of magnesium.

67. (New) The method of claim 66, wherein the concentration of magnesium is up to about

2.5 mM.

68. (New) The method of claim 1, wherein the active ingredients (i) and (ii) are administered together with another medicament.

69. (New) The method of claim 68, wherein the medicament is dipyridamole or a clot-busting drug.

70. (New) The method of claim 69, wherein the clot-busting drug is streptokinase.

71. (New) The method of claim 1, wherein the subject is a neonate/infant.

72. (New) The method of claim 4, wherein the administration in cardiovascular applications is achieved by mixing the active ingredients with the blood of the subject or a subject having a similar blood type.

73. (New) The method of claim 1, wherein the administration in cardiovascular applications is achieved by mixing the active ingredients with the blood of the subject or a subject having a similar blood type.

74. (New) The method of claim 1, wherein arrest is achieved by either continuous or intermittent delivery.

75. (New) The method of claim 1, wherein the arrest occurs at temperatures of about 15°C to about 37°C.

76. (New) A method for arresting, protecting or preserving an organ comprising adding a composition which includes effective amounts of (i) potassium channel opener or agonist or an adenosine receptor agonist and (ii) a local anaesthetic for use in arresting, protecting or preserving an organ.

77. (New) A pharmaceutical or veterinary composition comprising effective amounts of (i) a

potassium channel opener or agonist or an adenosine receptor agonist and (ii) a local anaesthetic.

78. (New) A composition as claimed in claim 77, wherein the potassium channel opener or agonist is selected from nicorandil, diazoxide, minoxidil, pinicadil, aprikalim, cromokulim, NS-1619 (1,3-dihydro-1-[2-hydroxy5(trifluoromethyl)phenyl]5-(trifluoromethyl)2-H-benimidazol-one), amlodipine, Bay K 8644(L-type)(1,4-dihydro-26-dimethyl-5-nitro-4[2(trifluoromethyl)phenyl]-3-pyridine carboxylic acid (methyl ester)), bepridil HC1 (L-type), calciseptine (L-type), omega-conotoxin GVIA (N-type), omega-conotoxin MVIIC (Q-type), cyproheptadine HC1, dantrolene sodium (Ca^{2+} release inhibitor), diltiazem HC1 (L-type), filodipine, flunarizine HC1 (Ca^{2+}/Na^{+}), fluspirilene (L-type), HA-1077 2HC1(1-(5 isoquinolinyl sulphonyl) homo piperazine.HC1), isradipine, loperamide HC1, manoalide (Ca^{2+} release inhibitor), nicardipine HC1 (L-type), nifedipine (L-type), niguldipine HC1 (L-type), nimodipine (L-type), nitrendipine (L-type), pimozide (L- and T- type), ruthenium red, ryanodine (SR channels), taicatoxin, verapamil HC1 (L-type), methoxy-verapamil HC1 (L-type), YS-035 HC1 (L-type)N[2(3,4-dimethoxyphenyl)ethyl]-3,4-dimethoxy N-methyl benzene ethaneamine HC1) and AV blockers.

79. (New) The composition of claim 77, wherein the adenosine receptor agonist is selected from N^6-cyclopentyladenosine (CPA), N-ethylcarboxamido adenosine (NECA), 2-[p-(2-carboxyethyl)phenethyl-amino-5'-N-ethylcarboxamido adenosine (CGS-21680),2-chloroadenosine, N^6-[2-(3,5-dimethoxyphenyl)-2-(2-methoxyphenyl]ethyladenosine, 2-chloro-N^6-cyclopentyladenosine (CCPA), N-(4-aminobenzyl)-9-[5-(methylcarbonyl)-beta-D-robofuranosyl]-adenine (AB-MECA), ([IS-[1a, 2b, 3b, 4a(S^*)]]-4-[7-[[2-(3-chloro-2-thienyl)-1-methyl-propyl]amino]-3H-imidazole[4,5-b]pyridyl-3-yl]cyclopentane carboxamide (AMP579, N^6-(R)-phenylisopropyladenosine (R-PLA), amnophenylethyladenosine 9APNEA) and cyclohexyladenosine (CHA).

80. (New) The composition of claim 77, wherein the local anaesthetic is selected from mexiletine, diphenylhydantoin, prilocaine, procaine, mipivacaine and Class 1B antiarrhythmic agents.

81. (New) The composition of claim 77, wherein the local anaesthetic is selected from mexiletine, diphenylhydantoin, prilocaine, procaine, mipivacaine and Class 1B antiarrhythmic agents.

82. (New) The composition of claim 77, wherein the composition is a cardioplegic or

cardioprotectant composition.

83. (New) The composition of claim 77, wherein active ingredients (i) and (ii) are administered together with a pharmaceutically acceptable carrier, diluent, adjuvant or excipient.

84. (New) The composition of claim 83, wherein the pharmaceutically acceptable carrier, diluent, adjuvant or excipient, is a buffer having a pH of about 6 to about 9.

85. (New) The composition of claim 83, wherein the pharmaceutically acceptable carrier, diluent, adjuvant or excipient, has low concentrations of potassium.

86. (New) The composition of claim 85, wherein the concentration of potassium is up to about 10mM.

87. (New) The composition of claim 84, wherein the buffer is Krebs-Henseleit, St. Thomas No. 2 solution, Tyrodes solution, Fremes solution, Hartmanns solution or Ringers-Lactate.

88. (New) The composition of claim 84, wherein the pharmaceutically acceptable carrier, diluent, adjuvant or excipient has low concentrations of magnesium.

89. (New) The composition of claim 88, wherein the concentration of magnesium is up to about 2. 5mM.

90. (New) The composition of claims 78 wherein the active ingredients (i) and (ii) are administered together with another medicament.

91. (New) The composition of claim 90, wherein the medicament is dipyridamole or a clot-busting drug.

92. (New) The composition of claim 91, wherein the clot-busting drug is streptokinase.

93. (New) The composition of claim 78, wherein the AV blocker is adenosine.